

MAR 12 2004

Attachment VII: 510(k) Summary

K040346
page 1 of 1

Sponsor: Eurosurgeal, SA
B.P.23-18, rue Robespierre
Beaurains, France 62217
Phone: 33-3-21215960, Fax: 33-3-21215970

Official Contact Person: Emmanuel Margerit, Regulatory Affairs and Quality Manager

Proprietary Trade Name: ORIA Top Clip System

Device Description: The ORIA Top Clip System includes components made from commercially pure titanium and titanium alloy described by ASTM Standards F67 GR2 and ASTM F136, respectively. These components are available in various designs and sizes that allow the surgeon to build an implant construct suited to a patient's anatomical and physiological requirements. The components include: pedicle screws, set screws, top locking clips and rods.

Intended Use: ORIA Top Clip System is indicated for skeletally mature patients: (1) having severe spondylolisthesis (Grades 3 and 4) at L5-S1 joint; (2) who are receiving fusions using autogenous bone graft only; (3) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (4) who are having the device removed after the development of solid fusion mass.

When used as a pedicle screw system in the non-cervical spine of skeletally mature patients, the ORIA Top Clip System is indicated for immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: (1) degenerative spondylolisthesis with objective evidence of neurological impairment, (2) fracture, (3) dislocation, (4) scoliosis, (5) kyphosis, (6) spinal tumor, and (7) failed previous fusion (pseudarthrosis).

Materials: The ORIA Top Clip System components are manufactured from implant grade materials of pure commercial titanium and titanium alloy described by ASTM Standards F67 GR2 and ASTM F136, respectively.

Substantial Equivalence: Documentation was provided which demonstrated the ORIA Top Clip System to be substantially equivalent to a previously cleared system. The substantial equivalence is based upon equivalence in fundamental scientific technology (manufacturing, attachment configuration, basic design and materials) and indications/intended use.



MAR 12 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Eurosurgical, SA
C/o Ms. Karen E. Warden, MEBE
REO Spine Line
7000 Hampton Center, Suite G1
Morgantown, West Virginia 26505

Re: K040346
Trade/Device Name: ORIA Top Clip System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNH, MNI
Dated: February 11, 2004
Received: February 12, 2004

Dear Ms. Warden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

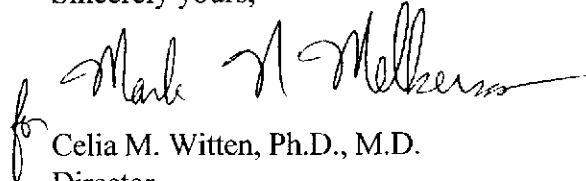
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - o Ms. Karen E. Warden, MEBE

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over a horizontal line.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

62-1

Attachment II: Indications for Use Statement

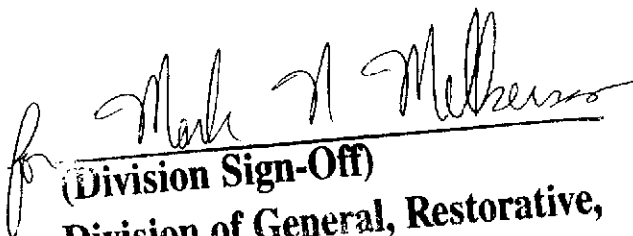
510(k) Number (if known): K040346

Device Name: **ORIA Top Clip System**

Indications for Use:

ORIA Top Clip System is indicated for skeletally mature patients: (1) having severe spondylolisthesis (Grades 3 and 4) at L5-S1 joint; (2) who are receiving fusions using autogenous bone graft only; (3) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (4) who are having the device removed after the development of solid fusion mass.

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(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K040346

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-the-Counter Use ☐